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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Gerardo Perez-Camargo

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EXAMINER

BARHAM, BETHANY P

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

10/08/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/510,126	Applicant(s) PEREZ-CAMARGO ET AL.	
	Examiner BETHANY BARHAM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2008 and 17 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-53,55 and 58-71 is/are pending in the application.
- 4a) Of the above claim(s) 38-47 and 61-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 48-53,55 and 58-60 is/are rejected.
- 7) ☒ Claim(s) 55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Applicant is reminded that the office has not received IDS as of this date.

Receipt of Applicant's Response filed on 6/18/08 is acknowledged. Claims 38-53, 55 and 58-71 are pending. Claims 38-47 and 61-71 remain withdrawn. Claims 48-53, 55 and 58-60 are rejected.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/17/08 has been entered.

Due to Applicant's Claim amendments and approved terminal disclaimers the 102/103 rejections and double patenting rejections of record are hereby withdrawn.

NEW REJECTIONS/OBJECTION

Claim 55 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

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dependent form, or rewrite the claim(s) in independent form. Claim 55 does not further limit claim 49 which depends from claim 48. Claim 48 claims a component "selected from the group consisting of whey protein and protease having the capacity to promote the formation of lipoproteins."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 48-53, 55 and 58-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification teaches that the intestinal mucosa function promoter may "include a fat transportation aid, agent, or carrier such as whey protein or a protease" (pg. 10, lines 14-15). The instant specification does not teach a % dry matter weight range for the "a fat transportation aid, agent, or carrier" as is instant claimed in claim 48. The specification does teach that the specific protease of papain can be included in an amount of about 0.1-1% or whey protein in an amount of about 2-10% dry matter weight (pg. 10, lines 15-19). The instant claim 48 generically claims protease, not papain specifically and thus the 0.1% does not read on all proteases only on papain; further the claim as written suggests that

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up to 10% protease or in the alternative 0.1% of whey protein can be added and this is outside the range supported in the instant specification. This is a new matter rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-53, 55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,471,999 ('999) in view of JP 408038063 ('063) or US 2001/0051206 ('206) and further in view of US 6,228,418 ('418).

The limitations of claims 48-53 are taught:

- '999 teach a pet milk powder as nutritional milk that results in reduced gastrointestinal intolerance (abstract). '999 teaches that the milk powder when administered in an effective amount with the nutritional composition reduces gastrointestinal intolerance and that it may further comprise one or more lipid source, protein source, vitamins and minerals, and teaches a specific aspect which comprises lactose (of micro-organism origin), lactase, taurine, arginine and choline (claims 1-9; col. 2, lines 9-lines 26).
- '999 teaches omega fatty acids such as soybean and rapeseed oil and in Examples 1-2 (col. 3, lines 15-20).

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- '999 teaches including an alkali in the milk-based powder, which slows the pH, drop in the gastrointestinal tract (col. 2, lines 53-55). '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40).
- '999 teaches chicory fibers, inulin, fructooligosaccharides with the probiotic micro-organism have a symbiotic relationship for promoting beneficial effects (col. 4, lines 9-14).
- '999 teaches that the amount of nutritional composition is to be fed to a mammal each day depends of factors such as age, type of mammal (dogs and cats), and other nutritional sources (col. 4, lines 25-36).
- Examples 1 and 2 teach mixing the milk powder, galactosidase (lactase amino), vitamins, minerals, and soybean oil, and adding water to provide nutritional supplement to dogs and puppies or cats.

The limitations of claims 54-55 and 58-60 are taught:

- '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40).
- '999 does not teach omega fatty acids derived from fish oil.
- '063 teaches a pet food composition with omega fatty acids, preferably fish oil (abstract).

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- '206 teaches a pet food composition including omega fatty acids such as flaxseed and fish oil (abstract, Example 1 and Table 1).
- '999, '063, and '206 do not teach an amount of whey protein as instant claimed in claim 48.
- '418 teaches a pet treat composition comprises approximately 2-15% weight of a protein, preferably whey protein (abstract; col. 1, lines 61-63, col. 3, lines 24-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a known omega-3-fatty acid of rapeseed oil ('999) for the fish oil of '063 and '206 in the pet food composition of '999. One of ordinary skill in the art would recognize that fish oil has a high content of omega-3-fatty acid, and that it is known to include fish oil in pet foods to treat diseases. One of ordinary skill in the art would be motivated to combine the teachings of '999 and '063 or '206 since both teach that fish oil included in a pet food composition has beneficial effects for decreasing inflammation and allergic response. All teach including omega-3-fatty acids in the pet food compositions provide nutritional and health benefit and it is within the purview of the skilled artisan to substitute one known omega fatty acid for another with a reasonable expectation of success. Further, one of ordinary skill in the art at the time the invention was made would look to '418 to know the specific amount of whey protein to include in the protein material of '999. A skilled artisan would be motivated to add whey protein of '999 and '418 can be added to a composition of '999 an amount of 2-15% weight as taught by '418 since the result is a highly palatable composition to pets. '999 teaches including whey protein in the milk powder and generically teaches milk

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powder in the amount 96.2% or 97.1% by weight (examples) and a skilled artisan would have a reasonable expectation of success incorporating the specific whey protein % of '418 into '999 for the purpose of obtaining a highly palatable composition and reduces the gastrointestinal intolerance.

Claims 48-53, 55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al., WO 02/15719 ('719) in view of JP 408038063 ('063) or US 2001/0051206 ('206) and further in view of US 6,228,418 ('418).

The limitations of claims 48-51 and 54 are taught:

- '719 discloses a method of treatment which comprises administering an effective amount of the composition which contains a lipid source including omega-3 fatty acids and whey protein (both intestinal mucosa function promoters according to applicant) to improve, promote, maintain intestinal function and mucins a patient or companion animal (abstract, claims 1-2 and 14-20, pg. 6 lines 5-10; pg. 12 lines 3-21). Example 4 teaches a nutritional supplement comprising whey protein and probiotic bacteria. '719 teaches that the nature of whey protein and the fact that it is capable of being easily digested, the composition has a beneficial effect in patients with limited appetite due illness, surgery, chronic gastritis, etc (pg. 4, line 31-pg. 5, line 6), and that the addition of a probiotic micro-organism provides the advantage of restoring the natural balance of the intestinal flora following antibiotic therapy (pg. 6, lines 7-10).

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- Whey protein is taught by applicant to be a fat transportation aid agent and carrier (instant spec pg. 10, 13-20).
- '719 also teaches including a prebiotic (claim 13, pg. 5, lines 27-30).
- '719 teaches omega-3-fatty acids of including the oils of rapeseed, canola, soy, hazelnut, etc (pg. 8, lines 15-24).

The limitations of claims 52-53 and 58-60 are taught:

- '719 teaches including taurine and vitamins (claim 12, pg. 5, lines 18-25; pg. 6, lines 27-29)
- '719 teaches a nutritional supplement comprising whey protein and omega-3 fatty acids (abstract, claims 1-2).
- '719 does not teach omega fatty acids derived from fish oil, but does teach a pet food composition comprising omega 3:6 fatty acid content ratio of about 5:1 to about 10:1 (abstract).
- '063 teaches a pet food composition with omega 3:6 fatty acids ration of 3:1 to 10:1 preferably 5:1 to 7.5:1, and preferably fish oil (abstract).
- '206 teaches a pet food composition including omega fatty acids such as flaxseed and fish oil with a ratio of 5:1 of omega 3:6 fatty acids (abstract, Example 1 and Table 1).
- '719, '063, and '206 do not teach an amount of whey protein as instant claimed in claim 48.
- '418 teaches a pet treat composition comprises approximately 2-15% weight of a protein, preferably whey protein (abstract; col. 1, lines 61-63, col. 3, lines 24-31).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a known omega-3-fatty acid of rapeseed oil ('719) for the fish oil of '063 and '206 in the pet food composition of '719. One of ordinary skill in the art would recognize that fish oil has a high content of omega-3-fatty acid, and that it is known to include fish oil in pet foods to treat diseases. One of ordinary skill in the art would be motivated to combine the teachings of '719 and '063 or '206 since both teach that fish oil included in a pet food composition in an amount of 5:1 ratio of omega 3:6 fatty acid has beneficial effects for decreasing inflammation and allergic response. All teach including omega fatty acids in a 5:1 ratio in the pet food compositions provide nutritional and health benefit and it is within the purview of the skilled artisan to substitute one known omega-3-fatty acid for another with a reasonable expectation of success. Further, one of ordinary skill in the art at the time the invention was made would look to '418 to know the specific amount of whey protein to include in the protein material of '719. A skilled artisan would be motivated to add whey protein of '719 and '418 can be added to a composition of '719 an amount of 2-15% weight as taught by '418 since the result is a highly palatable composition to pets. '719 teaches including whey protein in an amount of 4.8% by weight (examples) and a skilled artisan would have a reasonable expectation of success incorporating the specific whey protein % of '418 into '719 for the purpose of obtaining a highly palatable and reduces the gastrointestinal intolerance of composition.

Response to Arguments

Applicant's arguments with respect to claims 48-53, 55 and 58-60 have been considered but are moot in view of the new grounds of rejection necessitated by applicants' amendments. Applicants argued that '999 or '719 in view of '206 or '063 does not teach a specific amount of a "fat transportation aid, agent, or carrier" such as whey protein. The new rejections teach a % weight of whey protein, both '999 and '719 teach improved gut function and reduced gastrointestinal intolerance of a pet composition which includes whey protein and oil, '206 and '063 are relied upon to teach that fish oil is preferred and '418 teaches that whey protein is highly palatable when given to a pet in a composition in specifically in an amount of 2-15% by weight of the composition, as such the instant claims are obvious over the newly cited prior art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham
Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615